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PABST PATENT GROUP

NO. 0678 P. 1

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Our Docket No. ICI 102 Client/Matter No. 078230/00027  
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MESSAGE:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stefan Dietmar Anker and Andres Justin Stewart Coats

Serial No.: 09/807,558 Art Unit: 1647

Filed: July 17, 2001 Examiner: Fozia M. Hamud

For: METHODS OF TREATMENT

PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
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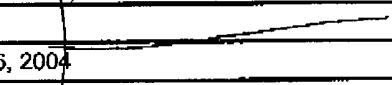
TRANSMITTAL  
FORM

(To be used for all correspondence after initial filing)

|  |  |                        |                |
|--|--|------------------------|----------------|
|  |  | Application Number     | 09/807,558     |
|  |  | Filing Date            | July 17, 2001  |
|  |  | First Named Inventor   | Stefan Dietmar |
|  |  | Art Unit               | 1647           |
|  |  | Examiner Name          | Fozia M. Hamud |
| Total Number of Pages in This Submission |  | Attorney Docket Number | ICI 102        |

| ENCLOSURES (Check all that apply)  |   |  |         |
|--|---|--|---------|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input checked="" type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br><input type="checkbox"/> Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance communication to Group<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input type="checkbox"/> Other Enclosure(s) (please identify below): | Remarks |

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|                         |   |                        |
|-------------------------|---|------------------------|
| Firm or Individual name | Patricia L. Pabst, Esq., Reg. No. 31,284<br>400 Colony Square, Suite 1200; 1201 Peachtree Street, N.E.; Atlanta, GA 30361 | Pabst Patent Group LLP |
| Signature               |                                        |                        |
| Date                    | July 6, 2004  |                        |

## CERTIFICATE OF TRANSMISSION/MAILING

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|-----------------------|---|------|--------------|
| Typed or printed name | Brian K. Adams  |      |              |
| Signature             |  | Date | July 6, 2004 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$ **130.00**)

**Complete if Known**

|                      |                |
|----------------------|----------------|
| Application Number   | 09/807,558     |
| Filing Date          | July 17, 2001  |
| First Named Inventor | Stefan Dietmar |
| Examiner Name        | Fozia M. Hamud |
| Art Unit             | 1647           |
| Attorney Docket No.  | ICI 102        |

**METHOD OF PAYMENT (check all that apply)**

Check  Credit card  Money Order  Other  None

Deposit Account

Deposit Account Number  
Deposit Account Name

**50-3129**

**Pabst Patent Group LLP**

The Director is authorized to: (check all that apply)

Charge fee(s) indicated below  Credit any overpayments  
 Charge any additional fee(s) or any underpayment of fee(s)  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity  | Small Entity  | Fee Description        | Fee Paid |
|---------------|---------------|------------------------|----------|
| Fee Code (\$) | Fee Code (\$) |                        |          |
| 1001 770      | 2001 385      | Utility filing fee     |          |
| 1002 340      | 2002 170      | Design filing fee      |          |
| 1003 530      | 2003 265      | Plant filing fee       |          |
| 1004 770      | 2004 385      | Reissue filing fee     |          |
| 1005 160      | 2005 80       | Provisional filing fee |          |

**SUBTOTAL (1) (\$)**

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

| Total Claims       | Extra Claims |      | Fee from below | Fee Paid |
|--------------------|--------------|------|----------------|----------|
|                    | 40           | 40*  |                |          |
| Independent Claims | 9            | .9** |                |          |
| Multiple Dependent |              |      |                |          |

| Large Entity  | Small Entity  | Fee Description  |
|---------------|---------------|--|
| Fee Code (\$) | Fee Code (\$) |  |
| 1202 18       | 2202 9        | Claims in excess of 20                                     |
| 1201 86       | 2201 43       | Independent claims in excess of 3                          |
| 1203 280      | 2203 145      | Multiple dependent claim, if not paid                      |
| 1204 66       | 2204 43       | ** Reissue independent claims over original patent         |
| 1205 18       | 2205 9        | ** Reissue claims in excess of 20 and over original patent |

**SUBTOTAL (2) (\$)**

\*or number previously paid, if greater. For Reissues, see above

**3. ADDITIONAL FEES**

Large Entity Small Entity

| Fee Code (\$) | Fee Code (\$) | Fee Description  | Fee Paid |
|---------------|---------------|--|----------|
| 1051 130      | 2051 65       | Surcharge - late filing fee or oath  |          |
| 1052 50       | 2052 25       | Surcharge - late provisional filing fee or cover sheet                     |          |
| 1053 130      | 1053 130      | Non-English specification  |          |
| 1612 2,520    | 1812 2,520    | For filing a request for ex parte reexamination                            |          |
| 1804 820*     | 1804 920*     | Requesting publication of SIR prior to Examiner action                     |          |
| 1805 1,840*   | 1805 1,840*   | Requesting publication of SIR after Examiner action                        |          |
| 1251 110      | 2251 55       | Extension for reply within first month                                     |          |
| 1252 420      | 2252 210      | Extension for reply within second month                                    |          |
| 1253 950      | 2253 475      | Extension for reply within third month                                     |          |
| 1254 1,480    | 2254 740      | Extension for reply within fourth month                                    |          |
| 1255 2,010    | 2255 1,005    | Extension for reply within fifth month                                     |          |
| 1401 330      | 2401 165      | Notice of Appeal   |          |
| 1402 330      | 2402 165      | Filing a brief in support of an appeal                                     |          |
| 1403 290      | 2403 145      | Request for oral hearing   |          |
| 1451 1,510    | 1451 1,510    | Petition to Institute a public use proceeding                              |          |
| 1452 110      | 2452 55       | Petition to revive - unavoidable   |          |
| 1453 1,330    | 2453 665      | Petition to revive - unintentional   |          |
| 1501 1,330    | 2501 665      | Utility issue fee (or reissue)   |          |
| 1502 480      | 2502 240      | Design issue fee   | 130      |
| 1503 640      | 2503 320      | Plant issue fee  |          |
| 1480 130      | 1480 130      | Petitions to the Commissioner  |          |
| 1807 50       | 1807 50       | Processing fee under 37 CFR 1.17(q)  |          |
| 1806 180      | 1806 180      | Submission of Information Disclosure Stmt                                  |          |
| 8021 40       | 8021 40       | Recording each patent assignment per property (times number of properties) |          |
| 1809 770      | 2809 385      | Filing a submission after final rejection (37 CFR 1.129(a))                |          |
| 1810 770      | 2810 385      | For each additional invention to be examined (37 CFR 1.129(b))             |          |
| 1801 770      | 2801 385      | Request for Continued Examination (RCE)                                    |          |
| 1802 900      | 1802 900      | Request for expedited examination of a design application                  |          |

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3) (\$)**

**130**

(Complete if applicable)

| Submitted By | Name (Print/Type) | Patricia L. Pabst | Registration No. (Attorney/Agent) | 31,284       | Telephone (404) 879-2151 |
|--------------|-------------------|-------------------|-----------------------------------|--------------|--------------------------|
| Signature    |                   |                   | Date                              | July 6, 2004 |                          |

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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NO. 0678 P. 4

JUL 06 2004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Stefan Dietmar Anker and Andres Justin Stewart Coats

**OFFICIAL**

Serial No.: 09/807,558

Art Unit: 1647

Filed: July 17, 2001

Examiner: Fozia M. Hamud

For: *METHODS OF TREATMENT*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**

Sir:

Pursuant to Pursuant to 37 C.F.R. § 1.144, applicants petition the Group Director to review the restriction requirement set forth in the Office Action mailed on January 6, 2004, as maintained in the Office Action mailed on May 3, 2004. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

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ICI 102  
078230/00027

U.S.S.N. 09/807,558

Filed: July 17, 2001

**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT****Remarks**

In the Office Action mailed January 6, 2004, the claims were divided into 16 groups.

The claims, as pending, are attached as an Appendix for the convenience of the Group Director.

Claim 1 is directed to a method of treating weight loss due to underlying disease in a patient the method comprising administering to the patient an effective amount of an agent which reduces sympathetic nervous system activity.

Group I        Claims 1-3, 19, 29-31, 35-36, 38-39, (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone.

Group II        Claims 1-2, 5, 6, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 6, drawn to a method of administering to a patient a chymase inhibitor.

Group III        Claims 1-2, 7, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 8, drawn to a method of administering to a patient a cathepsin inhibitor.

Group IV        Claims 1-2, 9, 11, 13, 15, 19, 23, 29-31, 35-36, 38-39, 41 (in part) and claims 10, 12, 16 and 24, drawn to a method of administering to a patient a receptor blocker.

Group V        Claims 1-2, 17, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 18, drawn to a method of administering to a patient a ganglion blocking agent.

Group VI        Claims 1-2, 19, 21, 29-31, 35-36, 38-39, 41 (in part) and claim 20, drawn to a method of administering to a patient an opiate.

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078230/00027

U.S.S.N. 09/807,558

Filed: July 17, 2001

**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**

Group VII      Claims 1-2, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 22, drawn to a method of administering to a patient a compound that inhibits the effect of scopolamine.

Group VIII      Claims 1-2, 19, 25, 29-31, 35-36, 38-39, 41 (in part) and claim 26, drawn to a method of administering to a patient a xanthine oxidase inhibitor.

Group IX      Claims 1-2, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 27, drawn to a method of administering to a patient an erythropoietin.

Group X      Claims 1, 19, 29-31, 35-36, 41 (in part) and claim 14, drawn to a method of administering to a patient a receptor agonist.

Group XI      Claims 38 and 39 (in part), drawn to a method of administering to a patient a digitalis alkaloid.

Group XII      Claims 38 and 39 (in part), drawn to a method of administering to a patient a growth hormone.

Group XIII      Claims 38 and 39 (in part), drawn to a method of administering to a patient an insulin like growth factor.

Group XIV      Claims 38 and 39 (in part), drawn to a method of administering to a patient an endothelin antagonist.

Group XV      Claims 38 and 39 (in part), drawn to a method of administering to a patient a TNF antagonist.

Group XVI      Claims 28, 37, 40 and 46-47, drawn to a method of electrically stimulating a patient's muscles.

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ICI 102  
078230/00027

U.S.S.N. 09/807,558

Filed: July 17, 2001

**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**

Applicants provisionally elected Group I, Claims 1-3, 19, 29-31, 35-36, 38-39, (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone with traverse.

***The Restriction Requirement is Improper.***

The Examiner has applied PCT rules for Unity of Invention because this application is a 371 of PCT/GB99/03302. PCT Rule 13.2 deals with the requirement of unity of invention and defines the method for determining whether the requirement is satisfied. "Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features".

The independent claims in the present application are sufficiently linked as to form a single general inventive concept defined by claim 1. This inventive concept finds expression in common technical features which define the inventive contribution that the claims invention makes over the prior art- specifically to treat weight loss by administering an inhibitor of sympathetic nervous system activity. The Examiner has improperly limited the scope of the claimed invention to a single species defined as one of several compounds, listed in dependent claim 2. Even as to this single species, the reference cited by the Examiner, Mueller and Ayres, J. Clin. Invest. 65: 338-346 (1980), does not teach or suggest the use of propanolol for the treatment of cachexia, nor has the examiner provided a basis in fact and/or technical reasoning to reasonably support the determination that this allegedly inherent characteristic of propanolol

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**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**

necessarily flows from the teachings of Mueller and Ayres. *In Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int'l, 1990).

At most, the claims should have been divided into the following groups along with an election of species for the compound to reduce sympathetic nervous system activity.

Group I: claims 1-27, 29-31, 35 and 36 drawn to a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity.

Group II: claims 28, 37, 46 and 47 drawn to a method of treating weight loss by electrically stimulating the patient's muscles.

Group III: claims 38-40 drawn to a method of enhancing exercise performance.

Group IV: claim 41 drawn to a method of treating weight loss associated with a cardiovascular disorder.

**The Claims meet the Unity of Invention Standards for Markush Practice**

PCT Rule 13.2 also governs so called Markush practice. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of similar nature where the following criteria are fulfilled:

- (A) all alternatives have a common property or activity, and
- (B)(1) a common structure is present,

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Filed: July 17, 2001

**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the present application, the claims have the common property/ activity of decreasing sympathetic nervous system activity and are all recognized as being sympathetic nervous system blockers. These are known compounds with recognized activities and classification, although not for treating weight loss.

**Division of Single Claims into Multiple Inventions is Improper**

It is improper to divide a single claim such as claim 1 into a plurality of inventions as the Examiner has done. Proper practice would be to require an election of species for search purposes. It is understood that once a species is determined to be free of prior art, the remaining species will also be searched.

The proper restriction in the instant application would be to divide the claims based on the method of treatment as described above and require an election of species for the compound to be administered.

Claims 1-27, 29-31, 35 and 36 all clearly define essential characteristics of the single embodiment of the invention that being *a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity*. The examiner has divided the generic claims into different groups based on description in the specification of what molecules can be used, *even in the complete absence of any such limitations in the claims!*

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U.S.S.N. 09/807,558

Filed: July 17, 2001

**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**

There is **no limitation** in the independent claim to specific compounds to inhibit sympathetic nervous system activity. Clearly, the examiner is trying to impose limitations not present in the claims through the vehicle of a restriction requirement, without examination under 35 U.S.C. § 102, 103 or 112.

It is stated in the MPEP that, "where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are but different definitions of the same disclosed subject matter, varying in breadth or scope of definition." (MPEP 806.03)

The case has already been pending for three years. In that time the Examiner has issued two restriction requirements and a letter requesting clarification- prosecution has been delayed.

The restriction requirement, by creating separate inventions out of the generic claims, makes it impossible to examine the claims in their entirety, and forces the applicants to restrict it to a single species. The examiner has no legal authority to require applicants to restrict a generic claim to a single species, absent prior art or lack of enablement.

**Summary**

The current restriction imposed on the claims of the present invention is improper. This restriction is inconsistent with the guidelines for restriction practice delineated by the MPEP and PCT rules. Upholding this restriction requirement would be to allow the examiner to impose limitations on the claims *which are not now present*.

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078230/00027

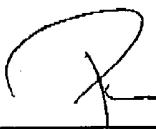
U.S.S.N. 09/807,558

Filed: July 17, 2001

**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**

Favorable consideration of this petition is earnestly solicited.

Respectfully submitted,



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Patricia L. Pabst  
Reg. No. 31,284

Date: July 6, 2004

PABST PATENT GROUP LLP  
400 Colony Square, Suite 1200  
1201 Peachtree Street  
Atlanta, Georgia 30361  
(404) 879-2151  
(404) 879-2160 (Facsimile)

**Certificate of Facsimile Transmission**

I hereby certify that this Petition for Reconsideration of Restriction Requirement, and any documents referred to as attached therein are being facsimile transmitted on the date shown below, to the Commissioner for Patents, U.S. Patent and Trademark Office, Alexandria, VA 22313-1450.



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Brian Adams

Date: July 6, 2004

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ICI 102  
078230/00027